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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,233	07/29/2003	Michael P. Schrom	03-003 (ANSI01-00015)	8284

37372 7590 07/14/2005

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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,233	SCHROM ET AL.	
	Examiner	Art Unit	
	Mark W. Bockelman	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20, 37-45 is/are pending in the application.
- 4a) Of the above claim(s) 37-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-18-04, 1-25-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 37-45 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The new subcombination claims that do not claim an electrode or connector are classified in electrical cables, requiring a new search, and recite the inner members in a fashion not claimed before or considered, requiring a researching in areas already searched.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim s 37-45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-11, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kordis et al. USPN 5,476,495.

Kordis shows and discusses the embedding of spiral wound conductors in a mapping probe catheter 18 lead body that is implanted into the body during procedures

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of mapping and ablation. For example, figures 31 –33 show a unitary wall member 96 of the mapping probe 18 having an inner portion 106 forming a lumen 108. An inner layer is shown having at least one conductor 110 as well as an outer layer 112 having at least one conductor, both layers being within the unitary wall. At least connector 44 communicates with a plethora of electrodes on the basket member 24. The mapping probe can be much smaller than 34 French (column 6 lines 46-50) and is made of materials Pebax and Teflon that can be used as extrusion materials.

Claims 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Diaz USPN 5,824,026 or Winkler USPN 5,555,618.

Diaz teaches a catheter with a unitary wall extending from the inner lumen to the wall 17, comprising an inner portion 32 that forms a lumen, an inner layer 34 and/or 42, an outer layer 36 and at least one electrode (see stripped region 20) that is inherently connected to a stimulus for depolarizing the heart (namely a defibrillator –see column 6 lines 25-35) through some sort of connector (be it a welded connection or pin). The inner layer 34 and/or 42 may additionally be connected to the sensor electrodes 22, 24, 26 for a total of 6 electrodes. Polyurethane which is considered an extrusion material (i.e. material that can be used in extrusion) is used in the outer covering 17 and therefore the unitary wall is comprised of an extrusion material. For the defibrillator embodiment the catheter is sized well below a 34 french diameter – column 6 lines 32-35.

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Winkler USPN 5,555,618 teaches a similar device with reference to figures 10-12.

Claims 10 –12, 14-17, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brownlee USPN 5,772,693.

Brownlee shows a catheter construction (see figure 20) with a unitary wall having an inner portion (see inner most coil 56 and inner most sheath 54) with an inner layer conductor (second inner most coil 56) and outer layer(third inner most or outer most coil) within the unitary wall. The catheter is formed with extrusion material on each of the coils followed by insertion and heat setting to achieve its shape. See column 5 lines 10-26 and column 12 lines 15-25 for instance. Connectors 914) are formed at the proximal end and in the embodiment of figure 13, 5 electrodes 22, 24, 80, 38 and 41 are shown. The device is connect to a pacemaker to provide a stimulus for pacing the heart.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 18are rejected under 35 U.S.C. 103(a) as being unpatentable over Brownlee USPN 5,772693. While Brownlee is silent to the cross-sectional size of

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the lead a size 34 french is very large and to have manufacture the Brownlee lead smaller than such would have been apparent to those of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 4-29-2005 have been fully considered but they are not persuasive. Applicant argues the meaning of "unitary" to be limited to something much narrower than its normal meaning. Unitary according to Webster's dictionary means "of or relating to a unit". The examiner considers the walls of each of the references applied, although some formed of composite structure, to form an electrode lead wall unit. Thus applicant argues more narrowly than that claimed.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 1-25-2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

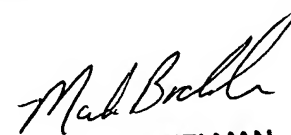
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

July 10, 2005


MARK BOCKELMAN
PRIMARY EXAMINER